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UTILITY PATENT APPLICATION TRANSMITTAL
(Only for new nonprovisional applications under 37 CFR 1.53(b))

JC926 U.S. PRO
09/692494
10/19/00

Docket No. : 39716/KMO/W112
 Inventor(s) : Kristine B. Fuimaono and Irma Hill
 Title : IRRIGATION PROBE FOR ABLATION
 DURING OPEN HEART SURGERY
 Express Mail Label No. : EL387001535US

ADDRESS TO: Assistant Commissioner for Patents
 Box Patent Application
 Washington, D.C. 20231

Date: October 19, 2000

1. FEE TRANSMITTAL FORM (*Submit an original, and a duplicate for fee processing*).

2. IF A CONTINUING APPLICATION

This application is a Continuation-in-Part of patent application No. 09/370,601.

Prior application information: Examiner Not Yet Assigned; Group Art Unit: 3762

This application claims priority pursuant to 35 U.S.C. §119(e) and 37 CFR §1.78(a)(4), to provisional Application No. .

3. APPLICATION COMPRISED OF

Specification

24 Specification, claims and Abstract (total pages)

Drawings

7 Sheets of drawing(s) (FIGS. 1 to 8)

Declaration and Power of Attorney

Newly executed
 Unexecuted declaration
 Copy from a prior application (37 CFR 1.63(d))(for continuation and divisional)

4. Microfiche Computer Program (Appendix)

5. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)

Computer Readable Copy
 Paper Copy (identical to computer copy)
 Statement verifying identity of above copies

6. ALSO ENCLOSED ARE

Preliminary Amendment
 A Petition for Extension of Time for the parent application and the required fee are enclosed as separate papers
 Small Entity Statement(s)
 Statement filed in parent application, status still proper and desired

**FEE TRANSMITTAL
UTILITY PATENT APPLICATION**

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FEE DETERMINATION

CLAIMS AS FILED					
	NUMBER FILED	NUMBER EXTRA	SMALL ENTITY RATE	LARGE ENTITY RATE	Fee
TOTAL CLAIMS	56 - 20	36	x \$9.00	36 x \$18.00	\$648.00
INDEPENDENT CLAIMS	4 - 3	1	x \$40.00	1 x \$80.00	\$80.00
MULTIPLE-DEPENDENT CLAIMS FEE			\$135.00	\$270.00	-0-
BASIC FEE			\$355.00	\$710.00	\$710.00
TOTAL FILING FEE					\$1,438.00

List Independent Claims: 1, 7, 34 and 42

METHOD OF PAYMENT

Payment Enclosed: Check for \$1,438.00

The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 and 1.17 which may be required during the **entire pendency** of the application to Deposit Account No. 03-1728. Please show our docket number with any charge or credit to our Deposit Account. **A duplicate copy of this sheet is enclosed.**

Respectfully submitted,

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By


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UTILITY PATENT APPLICATION TRANSMITTAL
(Only for new nonprovisional applications under 37 CFR 1.53(b))

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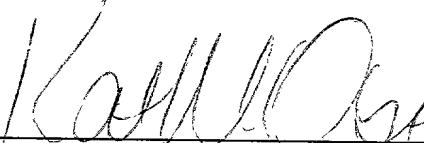
- Copy of Statement filed in provisional application, status still proper and desired
- An Assignment of the invention with the Recordation Cover Sheet and the recordation fee are enclosed as separate papers
- This application is owned by pursuant to an Assignment recorded at Reel
, Frame
- Information Disclosure Statement (IDS)/PTO-1449
 - Copies of IDS Citations
- Certified copy of Priority Document(s) (*if foreign priority is claimed*)
- English Translation Document (*if applicable*)
- Return Receipt Postcard (MPEP 503) (should be specifically itemized).
- Other

7. CORRESPONDENCE ADDRESS

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Respectfully submitted,

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By 
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626/795-9900

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**IRRIGATION PROBE FOR ABLATION
DURING OPEN HEART SURGERY**

CROSS-REFERENCE TO RELATED APPLICATION

5 This application is a continuation-in-part of U.S. Application No. 09/370,601, filed August 10, 1999, the disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

10 The present invention is directed to an irrigation ablation probe for use during open heart surgery.

BACKGROUND OF THE INVENTION

15 Atrial fibrillation is a common sustained cardiac arrhythmia and a major cause of stroke. This condition is perpetuated by reentrant wavelets propagating in an abnormal atrial-tissue substrate. Various approaches have been developed to interrupt wavelets, including surgical or catheter-mediated atriotomy. It is believed that to treat atrial fibrillation by radio-frequency ablation using a catheter, continuous linear lesions must be formed to segment the heart tissue. By segmenting the heart tissue, no electrical activity can be transmitted from one segment to another. Preferably, the segments are made too small to be able to sustain the fibrillatory process.

20 It has been found that over 60% of patients with mitral valve problems also have atrial fibrillation. Moreover, patients undergoing open heart surgery commonly develop atrial fibrillation during the surgery, and thus it would be useful to address this problem during the surgery. Accordingly, under certain circumstances it may be desirable to treat atrial fibrillation during open heart surgery, for example, when a patient is undergoing a mitral valve replacement or repair procedure. Accordingly, a need exists for devices and methods for treating atrial fibrillation during 25 open heart surgery.

SUMMARY OF THE INVENTION

The present invention is directed to an irrigation probe particularly useful for treating atrial fibrillation during open heart surgery. The probe of the present invention is also useful for other ablation and mapping procedures, particularly where irrigation of the ablation site is desired, such as for treating ventricular tachycardia. The invention is also directed to novel methods for treating atrial fibrillation with the probe of the invention. In accordance with the present invention, the probe comprises a rigid probe body and an irrigation electrode, which provides cooling and irrigation in the region of the tissue being ablated.

In one embodiment, the invention is directed to an irrigation ablation probe comprising a generally rigid probe body having proximal and distal ends. The probe body has an electrode at its distal end defining an inner cavity and having at least one irrigation opening through which fluid can pass and means for introducing fluid into the inner cavity. In a preferred embodiment an infusion tube having proximal and distal ends is in fluid communication with the inner cavity. In another preferred embodiment the infusion tube extends through the probe body for introducing fluid into the inner cavity of the electrode. In yet another preferred embodiment the electrode comprises an elongated body having first and second ends, which is fixedly attached, either directly or indirectly, to the distal end of the rigid probe body at a point along the elongated electrode body between its ends, wherein the angle formed between the distal end of the probe body and the electrode is greater than 0° . In still another preferred embodiment the electrode is attached generally perpendicular to the distal end of the rigid probe body and has at least three irrigation openings through which fluid can pass. In still yet another preferred embodiment the electrode comprises a flexible metal ribbon coiled around the outside of a looped irrigation tube fixedly attached, either directly or indirectly, to the distal end of the rigid probe body, where the irrigation tube has irrigation openings through which fluid can pass to the electrode and wherein the spaces between the coils provide openings through which fluid can pass to the outside of the irrigation probe.

In another embodiment, the invention is directed to an irrigation ablation probe. The probe comprises a generally rigid probe body as described above and a handle. The handle is mounted to the proximal end of the probe body. In a preferred embodiment, the generally rigid probe body

comprises a tubular body, an elongated electrode having first and second ends mounted to the distal end of the rigid probe body at a point along the elongated electrode body between its ends, wherein the angle formed between the distal end of the probe body and the electrode is greater than 0° , and a non-conductive sheath covering the length of the probe body. In still yet another embodiment the electrode comprises a flexible metal ribbon coiled around the outside of a looped irrigation tube fixedly attached either directly or indirectly to the distal end of the rigid probe body, where the irrigation tube has irrigation openings through which fluid can pass to the electrode and wherein the space between the coils provide openings through which fluid can pass to the outside of the irrigation probe.

In another preferred embodiment, the generally rigid probe body comprises tubing having proximal and distal ends and at least one lumen extending therethrough. An electrode as described above is mounted at the distal end of the tubing. The electrode has at least one irrigation opening through which fluid can pass. The probe body further comprises means for introducing fluid through the irrigation opening(s) of the electrode and a stiffening wire extending through a lumen of the tubing. A preferred means for introducing fluid comprises an infusion tube that extends through a lumen of the tubing with the distal end of the infusion tube in fluid communication with the one irrigation opening(s) in the electrode. In one embodiment, an elongated electrode having first and second ends is mounted to the distal end of the rigid probe body at a point along the elongated electrode body between its ends, wherein the angle formed between the distal end of the probe body and the electrode is greater than 0° . In a preferred embodiment the electrode is fixedly attached, either directly or indirectly, generally perpendicular to the rigid probe body and has at least three irrigation openings through which fluid can pass. In another preferred embodiment, the electrode comprises a flexible metal ribbon coiled around the outside of a looped irrigation tube fixedly attached either directly or indirectly to the distal end of the rigid probe body, where the irrigation tube has irrigation openings through which fluid can pass to the electrode and wherein the space between the coils provide openings through which fluid can pass to the outside of the irrigation probe.

In still another embodiment, the invention is directed to a method for treating atrial fibrillation in a patient. The method comprises opening the heart of the patient and ablating at least one linear lesion in the heart tissue using an irrigation probe as described above.

5 DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a side view of an embodiment of an irrigation probe according to the invention.

10 FIG. 2 is a side cross-sectional view of the handle of the irrigation probe of FIG. 1.

FIG. 3 is a perspective view of the distal end of the T-shaped irrigation probe of FIG. 1.

FIG. 4 is a side view of an alternative embodiment of an irrigation probe according to the invention.

15 FIG. 5 is a side cross-sectional schematic view of the distal end of the flexible metal ribbon irrigation probe of FIG. 4, wherein the rigid probe body comprises at least one lumen.

FIG. 6 is an end cross-sectional view of the distal end of the flexible metal ribbon irrigation probe of FIG. 4.

FIG. 7 is a side view of an alternative embodiment of an irrigation probe according to the invention.

20 FIG. 8 is a perspective view of the distal end of the flexible metal ribbon irrigation probe of FIG. 7.

DETAILED DESCRIPTION

The present invention is directed to an irrigation probe for use during open heart surgery.

25 In one embodiment, as shown in FIGs. 1 and 2, the irrigation probe **10** comprises a probe body **12** mounted to a handle **14**. The probe body **12** comprises a tubular body **16**, having proximal and distal ends, covered over by a non-conductive covering or sheath **18** along its length and an electrode **19** mounted at the distal end of the tubular body. The electrode **19** is a generally hollow tubular

structure having two ends **20** and defining an inner cavity therein. The electrode **19** is generally perpendicular to the tubular body **16** and fixedly attached to the tubular body **16** at a point between the two ends **20** of the electrode. The junction of the tubular body **16** and the electrode **19** forms an angle α that is greater than 0° , preferably greater than 10° , more preferably greater than 20° , even more preferably ranging from 70 to 110° , still more preferably ranging from 85 to 95° . Still more preferably the electrode is fixedly attached at an angle α of about 90° relative to the distal end of the probe body, thus forming a generally T-shaped arrangement. The tubular body **16** extends the entire length of the probe body **12**, with the proximal end of the tubular body extending into the handle **14** as described in more detail below. The probe body **12** preferably has a length (from the distal end of the handle to the distal end of the probe body) ranging from about 3.5 inches to about 12 inches, more preferably from about 5 to about 10 inches, still more preferably from about 7 to about 8 inches.

The tubular body **16** and the electrode **19** are both made of a material that is generally rigid so that the probe body **12** cannot bend during ablation, such as, for example, stainless steel (preferably 304VSS) or nitinol. Preferably the tubular body **16** and the electrode **19** have an inner diameter ranging from about 0.40 inch to about 0.80 inch, more preferably about 0.047 inch, and an outer diameter ranging from about 0.50 inch to about 0.90 inch, more preferably about 0.059 inch. If desired, the tubular body **16** and/or the electrode **19** can be heat-treated so that they are malleable enough to be bent by a physician to a desired shape but still rigid enough that they will not bend in use during a procedure. For example, for 304VSS stainless steel, the material is heated to about 800°F with electrical current or in a salt bath. The hollow interior of the tubular body **16** forms a lumen through which saline and the like may be conducted to the inner cavity of the electrode **19** and from there infused during a procedure, as described in more detail below. Alternatively the tubular body **16** could be solid and fluids could be introduced into the inner cavity of the electrode **19** by a separate external tube or the like.

The non-conductive sheath **18** extends from a proximal end inside the handle **14** to a distal end at the union of the tubular body **16** and the electrode **19**. The sheath **18** can be made of any suitable biocompatible non-conductive material, such as polyurethane. In this arrangement, the

electrode 19 is exposed, i.e., not covered by the sheath 18, for ablating tissue, mapping, etc. Preferably the length of the electrode 19 ranges from about 0.50 inch to about 1.5 inches, more preferably from about 0.75 inch to about 1.25 inches.

5 In the depicted embodiment, the length of the probe body 12 is approximately 7 inches. The proximal section of the probe body 12, i.e., the portion extending from the handle 14, is approximately 5.5 inches. The length of the electrode 19, is approximately 1 inch.

10 As shown in detail in FIG. 3, the electrode 19 has a series of irrigation openings 21 for passage of a cooling fluid out through the inner cavity of the electrode 19. The irrigation openings 21 can take any suitable shape, such as rectangular or oval slots or round holes. In a preferred embodiment the electrode 19 has at least three irrigation openings 21. The irrigation openings 21 are preferably in the section of the electrode 19 that is to be in contact with the tissue during a procedure, e.g., to enhance the cooling of an ablation site.

15 Saline or other suitable fluid is introduced into the inner cavity of the electrode 19 through any suitable means. In the embodiment of FIGS. 1 to 3, fluids are introduced into the inner cavity of the electrode 19 via the tubular body 16 through a luer hub 22 or the like at the proximal end of the probe 10. The luer hub 22 is connected to a flexible plastic tubing 24, e.g., made of polyimide. The plastic tubing 24 is attached, either directly or indirectly, to the proximal end of the tubular body 16, preferably within the handle 14, as shown in FIG. 2. Alternatively, the tubing 24 can be connected to a suction source (not shown) to permit aspiration of fluid from the region of tissue 20 being operated on.

25 As shown in FIG. 2, the handle 14 comprises a housing 26 having a generally open interior 28. The tubular body 16 and sheath 18 extend into the distal end of the handle housing 26. In the depicted embodiment, the sheath 18 terminates a short distance proximal to the distal end of the housing 26. The tubular body 16 continues proximally beyond the sheath 18. The flexible plastic tubing 24 extends into the proximal end of the handle housing 26. The plastic tubing 24 is attached to the tubular body 16 within the open interior 28 of the handle, preferably at a point proximal to the proximal end of the sheath 18. The plastic tubing 24 can be attached to the tubular

body **16** by any suitable means, for example, polyurethane glue. By this design, cooling fluid is introduced through the luer hub **22**, though the plastic tubing **24**, through the tubular body **16** and out the irrigation openings **21** in the electrode **19**.

Alternatively, fluid could be supplied to the electrode **19** and thereby the irrigation openings **21** via a separate irrigation tube (not shown) that can either run external to the tubular body **16** and attach directly to the electrode **19**, or can extend through the tubular body **16** to the electrode **19**. In either, case this separate irrigation tube could be made of any suitable material, e.g., plastic or metal, and attach to the electrode **19** by any direct or indirect means.

An electrode lead wire **30** having proximal and distal ends is electrically connected at or adjacent its distal end to the probe body **16**. The proximal end of the lead wire **30** is attached to a connector **32** for connection to a suitable source of ablation energy, e.g., radio frequency energy, or to an appropriate monitor. In the depicted embodiment, the lead wire **30** extends into the proximal end of the handle housing **26**. Within the open interior **28** of the handle **14**, the distal end of the lead wire **30** is wrapped around the portion of the tubular body **16** not covered by the sheath **18** and held in place by solder or the like. The portion of the lead wire **30** that extends outside the handle **14** is covered by a flexible plastic protective tubing **34**, e.g., made of polyimide.

An alternative embodiment of an irrigation probe according to the invention is shown in FIGs. 4 to 6. As shown in FIG. 4, the probe **10** comprises a probe body **12** and a handle **14**. The probe body **12** comprises a non-conductive tubing **40** having proximal and distal ends. In a particularly preferred embodiment, the non-conductive tubing **40** comprises outer and inner plastic walls, e.g., of polyurethane or polyimide, surrounding an imbedded braided mesh of stainless steel or the like. Preferably the tubing has an outer diameter of less than 8 French, more preferably less than 7 French. The tubing **40** has three lumens **42**, **44** and **46** extending along its length.

The irrigation probe comprises a metal ribbon electrode **47** at the distal end **48** of the non-conducting tube **40** comprising an exposed metallic ribbon **49** that is coiled around a loop of irrigation tubing **56**, both of which are indirectly or directly fixedly attached to the distal end **48** of the non-conducting tube **40**. As illustrated in FIG. 5, the probe's distal end **48** is generally solid,

having a fluid passage **50** and first and second blind holes **52** and **54** that correspond in size and location to the three lumens **46**, **42** and **44**, respectively, in the non-conductive tubing **40**. In the embodiment shown, the fluid passage **50** is in fluid communication with the inner cavity of the flexible irrigation tube **56**, which extends from the distal end of the fluid carrying lumen **46** out of the probe's distal end **48**. The irrigation tube **56** has a series of irrigation openings **57** for passage of a cooling fluid out through the spaces between the coils of the metallic ribbon **49**, as described in more detail below. The irrigation openings **57** can take any suitable shape, such as rectangular or oval slots or round holes. In a preferred embodiment the irrigation tubing **56** has at least three irrigation openings **57**. The irrigation openings **57** are preferably in the section of the irrigation tubing **56** corresponding to the section of the metal ribbon electrode **47** that is to be in contact with the tissue during an ablation procedure to enhance the cooling of the ablation site.

The metallic ribbon **49** is coiled loosely around the irrigation tube **56** such that fluid can pass unimpeded to the outside of the metal ribbon electrode **47**. The metal ribbon electrode **47**, as shown in detail in FIG. 5, comprises a continuous ribbon **49** of conducting metal, extending outside of the probe's distal end **48** and coiled about the flexible irrigation tube **56** in a loop, having a radius ranging from about 0.5 inch to 1.5 inches. The metal ribbon **49** can be coiled in any manner wherein the coils of the metal ribbon define an inner tubular passage through which the irrigation tube **56** runs and wherein the coils of metal ribbon **49** are generally spaced sufficiently far apart to allow fluid to escape through the irrigation passages. In a preferred embodiment the metal ribbon electrode **49** is coiled around from 1% to 100% of the length of the irrigation tube **56** that is outside the probe body **12**. More preferably, the metal ribbon **49** is coiled around from 20% to 80% of the length of the irrigation tube **56**, still more preferably the metal ribbon electrode is coiled around from 40% to 60% of the length of the irrigation tube **56**. The metal ribbon **49** can be made of any suitable material, and is preferably machined from a .005 inch thick ribbon of nitinol.

The metal ribbon **49** and the irrigation tube **56** can be attached to the probe's distal end **48** in any suitable manner. In the depicted embodiment, the metal ribbon **49** and the irrigation tube **56** are each attached at both ends to the probe's distal end **48** by a polyurethane glue seal **58** or the like.

However, any other means for fixedly mounting the metal ribbon **49** and the irrigation tube **56** on the probe's distal end **48** can also be used. For example, only one end of the metal ribbon **49** and/or the irrigation tube **56** may be attached to the probe's distal end **48**.

The metal ribbon electrode **47** is connected to a lead wire **67** having proximal and distal ends.

5 The proximal end of the lead wire **67** for the metal ribbon electrode **47** extends through the third lumen **46** of tubing **40** and through the handle **14**. The distal end of the lead wire **67** for the metal ribbon electrode **47** extends through the third lumen **46** and is attached to the metal ribbon electrode **47** by any conventional technique, for example, by soldering.

10 In the embodiment shown, a mapping ring electrode **62** is mounted on the tubing **40** proximal to the probe's distal end **48**. It is understood that the presence and number of ring electrodes may vary as desired. The ring electrode **62** is slid over the tubing **40** and fixed in place by glue or the like. The ring electrode **62** can be made of any suitable material, and is preferably machined from platinum-iridium bar (90% platinum/10% iridium).

15 The ring electrode **62** is connected to a lead wire **64** having proximal and distal ends. The proximal end of the lead wire **64** for the ring electrode **62** extends through the first lumen **42** of tubing **40** and through the handle **14**. The lead wire **64** can be connected to the ring electrode **62** by any conventional technique. Connection of the lead wire **64** to the ring electrode **62** is preferably accomplished by first making a small hole through the tubing **40**. Such a hole can be created, for example, by inserting a needle through the tubing **40** and heating the needle sufficiently to form a permanent hole. The lead wire **64** is then drawn through the hole by using a microhook or the like. The ends of the ring electrode lead wire **64** are then stripped of any coating and soldered or welded to the underside of the ring electrode **62**, which is then slid into position over the hole and fixed in place with polyurethane glue or the like. Any other means for fixedly mounting the ring electrode **62** to the tubing **40** can also be used

20 25 Both lead wires **64** and **67** terminate at their proximal end in a connector **32** that may be plugged into an appropriate monitor and/or source of radio frequency or other ablation energy. The portion of the lead wires **64** and **67** extending out the proximal end of the handle **14** are enclosed

within a protective tubing 34, which can be made of any suitable material, preferably polyimide, as shown in FIG. 4.

An infusion tube 72 is provided for infusing fluids, e.g., saline, to cool the metal ribbon electrode 47 during ablation. The infusion tube 72 may also be used to infuse drugs to the ablation site. The infusion tube 72 may be made of any suitable material, and is preferably made of polyimide tubing. The infusion tube 72 has proximal and distal ends, with its distal end mounted in the fluid passage 50 of the probe's distal end 48 by any suitable method, e.g., by polyurethane glue or the like. The infusion tube 72 extends from the probe's distal end 48, through the third lumen 46 of the tubing 40, and through the handle 14. As would be recognized by one skilled in the art, the distal end of the infusion tube 72 can be positioned at any point within the third lumen 46. The proximal end of the infusion tube 72 ends in a luer hub 22 or the like. Any other means for infusing fluids to the metal ribbon electrode 47 can also be used, including running the infusion tube 72 external to the tubing 40 and fluid passage 50.

A stiffening wire 74, having proximal and distal ends, is mounted in the second lumen 44 of the tubing 40. The stiffening wire 74 is made of a rigid metal or plastic material, preferably stainless steel, to prevent the probe body 12 from bending during a procedure. If desired, the stiffening wire 74 can be heat-treated so that it is malleable and can be bent to a desired shape before use, but still rigid enough that it will not bend in use during a procedure. A non-conductive tube 76, preferably made of polyimide, is attached to the distal end of the stiffening wire 74 for mounting the stiffening wire in the probe's distal end 48. The non-conductive tube 76 extends out of the second lumen 44 and into the second blind hole 54 in the probe's distal end 48, and is secured in place by polyurethane glue or the like. Any other means for securing the stiffening wire 74 within the probe can also be used. The proximal end of the stiffening wire 74 terminates in the handle 14 or near the proximal end of the probe body 12.

While FIGs. 4 to 6 depict an irrigation probe 10 having a metal ribbon electrode 47, it will be understood that the irrigation probe 10 described above and illustrated in FIGs. 4 to 6 could also house the generally T-shaped electrode 19 illustrated in FIGs. 1 to 3. In this embodiment the

generally T-shaped electrode **19** is fixedly attached, either directly or indirectly, to the probe's distal end **48** such that the fluid passage **50** is in fluid communication with the inner cavity of the generally T-shaped electrode **19**. The construction and function of the lumens **42**, **44**, and **46**, and the remainder of the probe **10** would be similar to that described above and shown in FIGs. 4 to 6.

5 In another embodiment, as shown in FIGs. 7 and 8, the irrigation probe **10** comprises a probe body **12** mounted to a handle **14**, which is described in detail above. The probe body **12** comprises a tubular body **16**, having proximal and distal ends, covered over by a non-conductive covering or sheath **18**. In this embodiment, a metal ribbon electrode **35** comprising a coiled metal ribbon **33** and a loop of flexible irrigation tube **36** is disposed at the distal end of the probe body **12** and fixedly attached, either directly or indirectly, to the distal end of the tubular body **16**. The probe body **12** preferably has a length (from the distal end of the handle to the distal end of the probe body) ranging from about 3.5 inches to about 12 inches, more preferably from about 5 to about 10 inches, still more preferably from about 7 to about 8 inches.

10

15 The tubular body **16** is made of a material that is generally rigid so that the probe body **12** cannot bend during ablation, such as, for example, stainless steel (preferably 304VSS) or nitinol. Preferably the tubular body **16** has an inner diameter ranging from about 0.40 inch to about 0.80 inch, more preferably about 0.047 inch, and an outer diameter ranging from about 0.50 inch to about 0.90 inch, more preferably about 0.059 inch. If desired, the tubular body **16** can be heat-treated so that it is malleable enough to be bent by a physician to a desired shape but still rigid enough that it will not bend in use during an ablation procedure. The hollow interior of the tubular body **16** forms a lumen through which saline and the like may be conducted to the irrigation tube **36** of the metal ribbon electrode **35** and from there infused during an ablation procedure, as described in more detail below. Alternatively, the tubular body **16** could be solid, in which case fluids could be introduced into the irrigation tube **36** via a separate external tube or the like.

20

25 The non-conductive sheath **18** extends from the proximal end of the tubular body **16** inside the handle **14** to the distal end of the tubular body at the union of the tubular body **16** and the metal ribbon electrode **35**. The sheath **18** can be made of any suitable biocompatible non-conductive material, such as polyurethane. Preferably the diameter of the loop of the metal ribbon electrode **35**

ranges from about 0.50 inch to about 1.5 inches, more preferably from about 0.75 inch to about 1.25 inches.

In the depicted embodiment, the length of the probe body 12 is approximately 7 inches. The proximal section of the probe body 12, i.e., the portion extending from the handle 14, is approximately 5.5 inches. The diameter of the loop of the metal ribbon electrode 35 is approximately 1 inch.

As shown in detail in FIG.8, the metal ribbon electrode 35 comprises an irrigation tube 36 having first and second ends 37, at least one of which is fixedly attached either directly or indirectly to the tubular body 16, similar to the embodiment depicted in FIGs. 4 to 6. The irrigation tube 36 is bent so as to form a loop and the metal ribbon 33 is in turn coiled around the irrigation tube 36 and fixedly attached, either directly or indirectly, to the tubular body 16. In one preferred embodiment, the metal ribbon 33 and irrigation tube 36 are both attached to the tubular body 16 at both ends by any direct or indirect means, e.g., via a glue seal 38 as shown above in FIG. 5. Any other means for attaching the metal ribbon 33 and the irrigation tube 36 can also be used.

As shown, the irrigation tube 36 has a series of irrigation openings 39 for passage of a cooling fluid out through the metal ribbon 33. The irrigation openings 39 can take any suitable shape, such as rectangular or oval slots or round holes. In a preferred embodiment, shown in FIG. 8, the irrigation tube 36 has at least three irrigation openings 39. The irrigation openings 39 are preferably in the section of the irrigation tube 36 corresponding to the section of the metal ribbon 33 that is to be in contact with the tissue during a procedure, e.g., to enhance the cooling of the ablation site. The metal ribbon 33 is coiled loosely around the irrigation tube 36 such that fluid can pass unimpeded through the metal ribbon 33.

Saline or other suitable fluid is introduced into the tubular body 16 through a luer hub 22 or the like at the proximal end of the probe 10. The luer hub 22 is connected to a flexible plastic tubing 24, e.g., made of polyimide. The plastic tubing 24 is attached, either directly or indirectly, to the proximal end of the tubular body 16, preferably within the handle 14, as shown in FIG. 7. By this design, cooling fluid is introduced through the luer hub 22, though the plastic tubing 24, through the

tubular body 16, through the first and second ends 37 of the irrigation tube 36 and out the irrigation openings 39.

The irrigation probe shown in various embodiments in FIGs. 1 to 8, having either a metal ribbon electrode or a generally T-shaped electrode, can be used in any manner in which a standard probe can be used. For example, the above described probes can be used during open heart surgery for ablation. During an ablation procedure, the heart is opened and the irrigated electrode is used to form continuous linear lesions by ablation. As used herein, a linear lesion refers to any lesion, whether curved or straight, between two anatomical structures in the heart that is sufficient to block a wavelet, i.e., forms a boundary for the wavelet. Anatomical structures, referred to as "atrial trigger spots", are those regions in the heart having limited or no electrical conductivity and are described in Haissaguerre et al., "Spontaneous Initiation of Atrial Fibrillation by Ectopic Beats Originating in the Pulmonary Veins", New England Journal of Medicine, 339:659-666 (Sept. 3, 1998), the disclosure of which is incorporated herein by reference. The linear lesions typically have a length of from about 1 cm to about 4 cm, but can be longer or shorter as necessary for a particular procedure.

The probe described in FIGs 1 to 3 having a long tubular electrode is particularly useful for this procedure because it can create relatively long lesions. The probe depicted in FIGs. 4 to 6 above, having a smaller but flexible ablation electrode, is useful if the surgeon does not want to ablate as much tissue or wants to ablate a more precise lesion. The above-described probe having a flexible body is particularly useful if the surgeon needs to have a probe that conforms to a particular site to better ablate a desired region of tissue. Additionally, the flexible electrode is particularly useful for ablating locations where it is desirable to have the electrode conform to the tissue, rather than having the tissue conform to the electrode, for example, an atrial appendage. Further, the circular coil design can be used to form a generally circular region around an orifice of a tubular structure, such as a pulmonary vein, the coronary sinus, the superior vena cava, or the inferior vena cava. Once the heart is closed, the surgeon can use the probe on the outside of the heart, not only to ablate, but to verify that the electrical conduction has been stopped using the mapping electrodes. As would be

recognized by one skilled in the art, the probes of the present invention can be used during open heart surgery for other procedures as well.

The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention.

Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.

Claims:

1. An irrigation probe comprising:

a generally rigid probe body having proximal and distal ends;

an electrode comprising an elongated electrode body having first and second ends, wherein

5 the electrode defines an inner cavity, the electrode having at least one irrigation opening through which fluid can pass from the inner cavity to the outside of the electrode, the electrode being fixedly attached to the distal end of the probe body at a point along the elongated body of the electrode between the first and second ends wherein the distal end of the probe body and the electrode form an angle α greater than 0° ; and

10 means for introducing fluid into the inner cavity.

2. An irrigation probe according to claim 1, wherein the means for introducing fluid into the inner cavity comprises an infusion tube having proximal and distal ends wherein the distal end of the infusion tube is in fluid communication with the inner cavity.

15 3. An irrigation probe according to claim 2, wherein the infusion tube extends through the probe body.

20 4. An irrigation probe according to claim 2, wherein the probe body, the infusion tube and the electrode together comprise a single unitary generally hollow body.

5. An irrigation probe according to claim 1, further comprising a handle mounted at the proximal end of the probe body, the handle comprising a housing having a generally open interior.

25 6. An irrigation probe according to claim 1, wherein the generally rigid probe body comprises a malleable material.

7. An irrigation probe comprising:

a generally rigid probe body having proximal and distal ends;

an electrode comprising an elongated electrode body having first and second ends, wherein the electrode defines an inner cavity, the electrode having at least one irrigation opening through which fluid can pass from the inner cavity to the outside of the electrode, the electrode being fixedly attached to the distal end of the probe body at a point along the elongated body of the electrode between the first and second ends wherein the distal end of the probe body and the electrode form an angle α greater than 0° ;

5 a handle mounted to the proximal end of the probe body; and

10 an infusion tube having proximal and distal ends, wherein the distal end of the infusion tube is in fluid communication with the inner cavity.

15 8. An irrigation probe according to claim 7, wherein the infusion tube extends through the probe body.

15 9. An irrigation probe according to claim 7, wherein the generally rigid probe body and the electrode together comprise:

a single generally hollow tubular body that forms the infusion tube; and

20 a non-conductive sheath covering a portion of the tubular body proximal to the electrode.

20 10. An irrigation probe according to claim 9, wherein the tubular body has an inner diameter ranging from about 0.40 inch to about 0.80 inch and an outer diameter ranging from about 0.50 inch to about 0.90 inch.

25 11. An irrigation probe according to claim 9, wherein the tubular body has an outer diameter ranging from about 0.50 inch to about 0.70 inch.

12. An irrigation probe according to claim 9, wherein the tubular body has an inner diameter ranging from about 0.40 inch to about 0.60 inch.

13. An irrigation probe according to claim 7, wherein the rigid probe body is made of a malleable material.

14. An irrigation probe according to claim 9, further comprising a flexible plastic tubing attached to the proximal end of the tubular body for introducing fluid into the inner cavity of the electrode.

15. An irrigation probe according to claim 7, wherein the at least one irrigation opening is located on the surface of the electrode to be in contact with the tissue to be ablated.

16. An irrigation probe according to claim 7, wherein the at least one irrigation opening comprises at least three holes arranged along the length of the elongated body of the electrode.

17. An irrigation probe according to claim 7, wherein the probe body has a length ranging from about 3.5 inches to about 12 inches.

18. An irrigation probe according to claim 7, wherein the probe body has a length ranging from about 5 inches to about 10 inches.

19. An irrigation probe according to claim 7, wherein the electrode has a length ranging from about 0.50 inch to about 1.5 inches.

20. An irrigation probe according to claim 7, wherein the electrode has a length ranging from about 0.75 inch to about 1.25 inches.

21. An irrigation probe according to claim 7, wherein the angle α formed between the distal end of the probe body and the elongated electrode body is greater than about 10° .

22. An irrigation probe according to claim 7, wherein the angle α formed between the distal end of the probe body and the elongated electrode body is greater than about 20° .

23. An irrigation probe according to claim 7, wherein the angle α formed between the distal end of the probe body and the elongated electrode body ranges from about 70° to about 110° .

24. An irrigation probe according to claim 7, wherein the angle α formed between the distal end of the probe body and the elongated electrode body ranges from about 85° to about 95° .

10 25. An irrigation probe according to claim 7, wherein the point along the elongated body is approximately equidistant between the first and second ends.

15 26. An irrigation probe according to claim 7, wherein the generally rigid probe body comprises:

tubing having proximal and distal ends and first and second lumens extending therethrough, wherein the electrode is mounted at the distal end of the tubing; and

a stiffening wire having proximal and distal ends that extends through the second lumen of the tubing;

20 wherein the infusion tube extends at least a part of the way through the first lumen of the tubing, wherein the distal end of the infusion tube is in fluid communication with the inner cavity of the electrode.

27. An irrigation probe according to claim 26, wherein the stiffening wire is made of a malleable material.

25 28. An irrigation probe according to claim 26, wherein the at least one irrigation opening is located on the surface of the electrode to be in contact with the tissue to be ablated.

29. An irrigation probe according to claim 26, wherein the at least one irrigation opening comprises at least three holes arranged along the length of the elongated body of the electrode.

30. An irrigation probe according to claim 26, wherein the probe body has a length ranging
5 from about 3.5 inches to about 12 inches.

31. An irrigation probe according to claim 26, wherein the probe body has a length ranging
10 from about 5 inches to about 10 inches.

32. An irrigation probe according to claim 26, wherein the probe body has a length ranging
from about 7 inches to about 8 inches.

33. A method for treating atrial fibrillation in a patient comprising:
opening the heart of the patient; and
15 ablating at least one linear lesion in the heart tissue using an irrigation probe as recited in
claim 8.

34. An irrigation probe comprising:
a generally rigid probe body having proximal and distal ends;
20 a generally flexible irrigation tube having first and second ends, the irrigation tube defining
an inner cavity, wherein the irrigation tube generally forms a loop and at least one end is fixedly
attached to the distal end of the probe body, the irrigation tube having at least one irrigation opening
through which fluid can pass from the inner cavity to the outside of the irrigation tube;
means for introducing fluid into the inner cavity of the irrigation tube; and
25 an electrode comprising a flexible metal ribbon having first and second ends, wherein the
metal ribbon is coiled around the irrigation tube to form coils, and wherein space is provided between
the coils to allow fluid to pass from the irrigation tube to the outside of the electrode.

35. An irrigation probe according to claim 34, wherein both the first and second ends of the irrigation tube are fixedly attached to the distal end of the probe body.

5 36. An irrigation probe according to claim 34, wherein the first and second ends of the electrode are fixedly attached to the distal end of the probe body.

10 37. An irrigation probe according to claim 34, wherein the probe further comprises an electrode lead wire with proximal and distal ends wherein the proximal end of the electrode lead wire is electrically connected to a source of ablation energy and the distal end of the electrode lead wire is electrically connected to the electrode.

15 38. An irrigation probe according to claim 34, wherein the means for introducing fluid into the inner cavity comprises an infusion tube having proximal and distal ends, wherein the distal end of the infusion tube is in fluid communication with the inner cavity.

20 39. An irrigation probe according to claim 38, further comprising a handle mounted at the distal end of the probe body, the handle comprising a housing having a generally open interior.

40. An irrigation probe according to claim 34, wherein the generally rigid probe body comprises a malleable material.

25 41. An irrigation probe according to claim 34, wherein the flexible metal ribbon is made of nitinol.

42. An irrigation probe comprising:
a generally rigid probe body having proximal and distal ends;
a generally flexible irrigation tube having first and second ends, the irrigation tube defining an inner cavity, wherein the irrigation tube generally forms a loop and at least one end is fixedly

attached to the distal end of the probe body, the irrigation tube having at least one irrigation opening through which fluid can pass from the inner cavity to the outside of the irrigation tube;

an electrode comprising a flexible metal ribbon having first and second ends, wherein the metal ribbon is coiled around the irrigation tube to form coils, and wherein space is provided between the coils to allow fluid to pass from the irrigation tube to the outside of the electrode;

5 a handle mounted to the proximal end of the probe body; and

an infusion tube having proximal and distal ends, wherein the distal end of the infusion tube is in fluid communication with the inner cavity.

10 43. An irrigation probe according to claim 42, wherein the generally rigid probe body

comprises:

a generally rigid tubular body having proximal and distal ends, wherein the tubular body has at least one irrigation opening at its distal end through which fluid can pass to the inner cavity of the irrigation tube; and

15 a non-conductive sheath covering the tubular body.

44. An irrigation probe according to claim 43, wherein the tubular body has an inner diameter ranging from about 0.40 inch to about 0.80 inch and an outer diameter ranging from about 0.50 inch to about 0.90 inch.

20 45. An irrigation probe according to claim 43, wherein the tubular body is made of a malleable material.

46. An irrigation probe according to claim 43, further comprising a flexible plastic tubing
25 attached to the proximal end of the tubular body for introducing fluid into the tubular body.

47. An irrigation probe according to claim 42, wherein the probe body has a length ranging from about 3.5 inches to about 12 inches.

48. An irrigation probe according to claim 42, wherein the probe body has a length ranging from about 7 inches to about 8 inches.

49. An irrigation probe according to claim 42, wherein the loop has a diameter ranging 5 from about 0.50 inch to about 1.5 inches.

50. An irrigation probe according to claim 42, wherein the loop has a diameter ranging from about 0.75 inch to about 1.25 inches.

10 51. An irrigation probe according to claim 42, wherein the metal ribbon is made of nitinol.

52. An irrigation probe according to claim 42, wherein the generally rigid probe body comprises:

15 tubing having proximal and distal ends and first and second lumens extending therethrough, wherein the irrigation tube and electrode are mounted at the distal end of the tubing;

an infusion tube that extends at least part of the way through the first lumen of the tubing, wherein the distal end of the infusion tube is in fluid communication with the inner cavity of the irrigation tube; and

20 a stiffening wire having proximal and distal ends that extends through the second lumen of the tubing.

53. An irrigation probe according to claim 52, wherein the stiffening wire is made of a malleable material.

25 54. An irrigation probe according to claim 52, wherein the probe body has a length ranging from about 3.5 inches to about 12 inches.

55. An irrigation probe according to claim 52, wherein the probe body has a length ranging from about 7 inches to about 8 inches.

56. A method for treating atrial fibrillation in a patient comprising:
opening the heart of the patient; and
ablation at least one linear lesion in the heart tissue using an irrigation probe as recited in
claim 42.

IRRIGATION PROBE FOR ABLATION DURING OPEN HEART SURGERY

ABSTRACT

5 An irrigation probe useful for ablation during open heart surgery is provided. The irrigation probe comprises a generally rigid probe body and a handle mounted to the proximal end of the probe body. The generally rigid probe body has an electrode at its distal end having at least one irrigation opening through which fluid can pass. An infusion tube extends through the probe body for introducing fluid to the electrode.

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FIG. 1

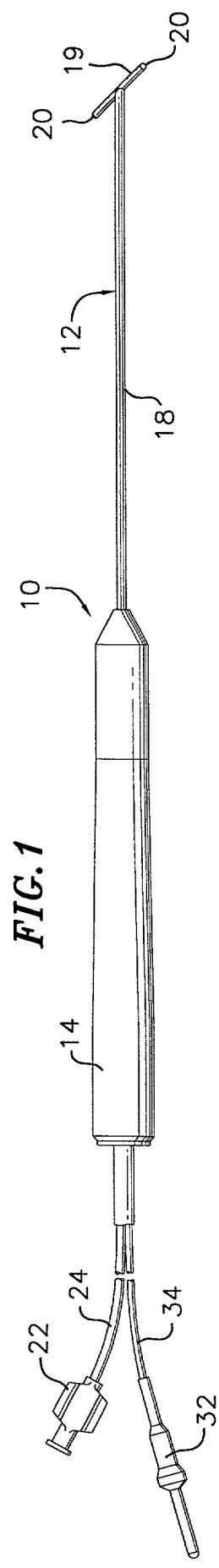


FIG. 2

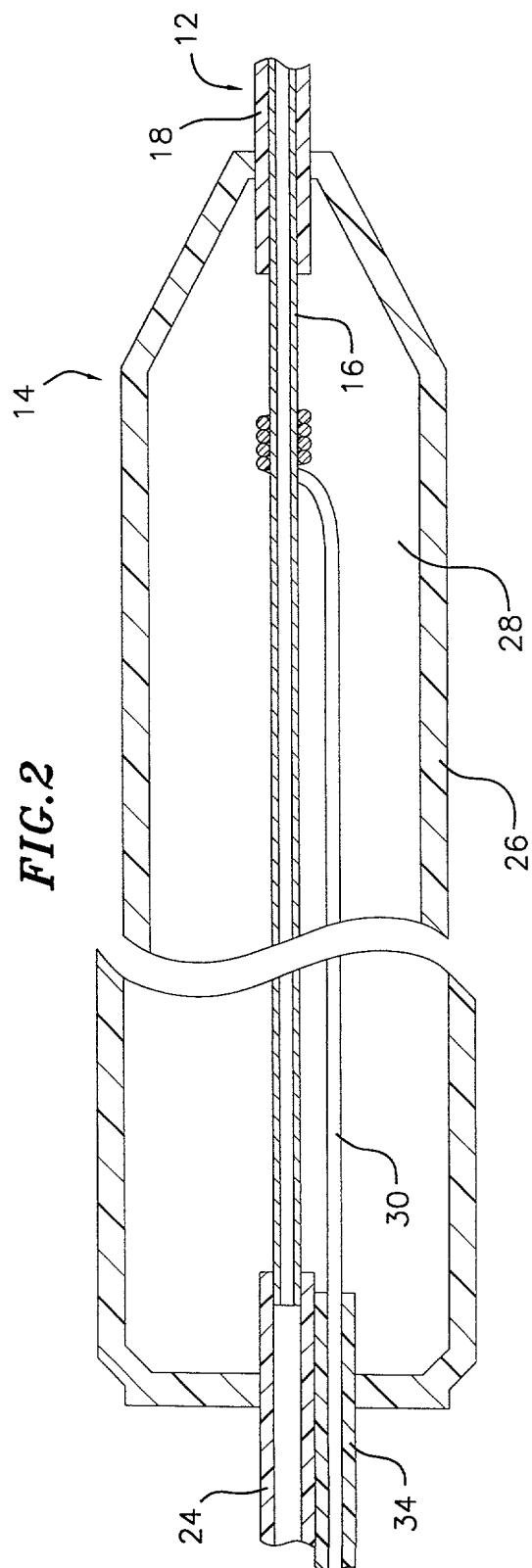
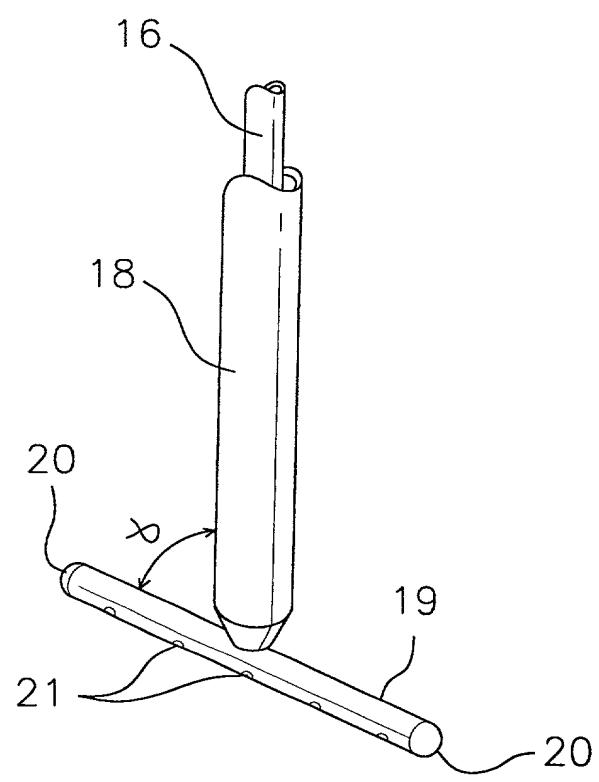
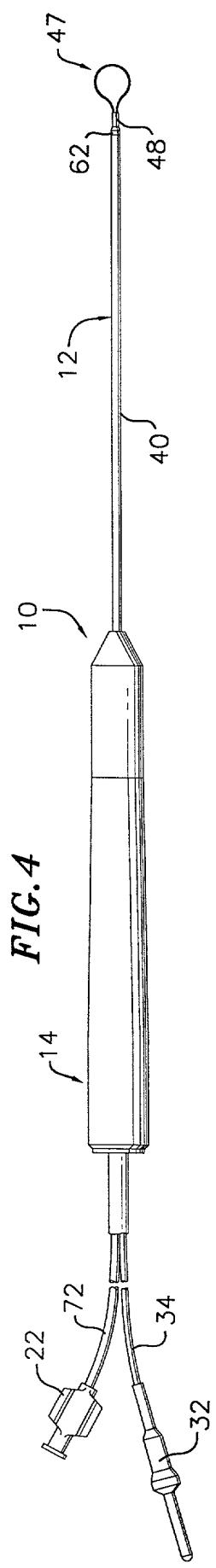


FIG. 3





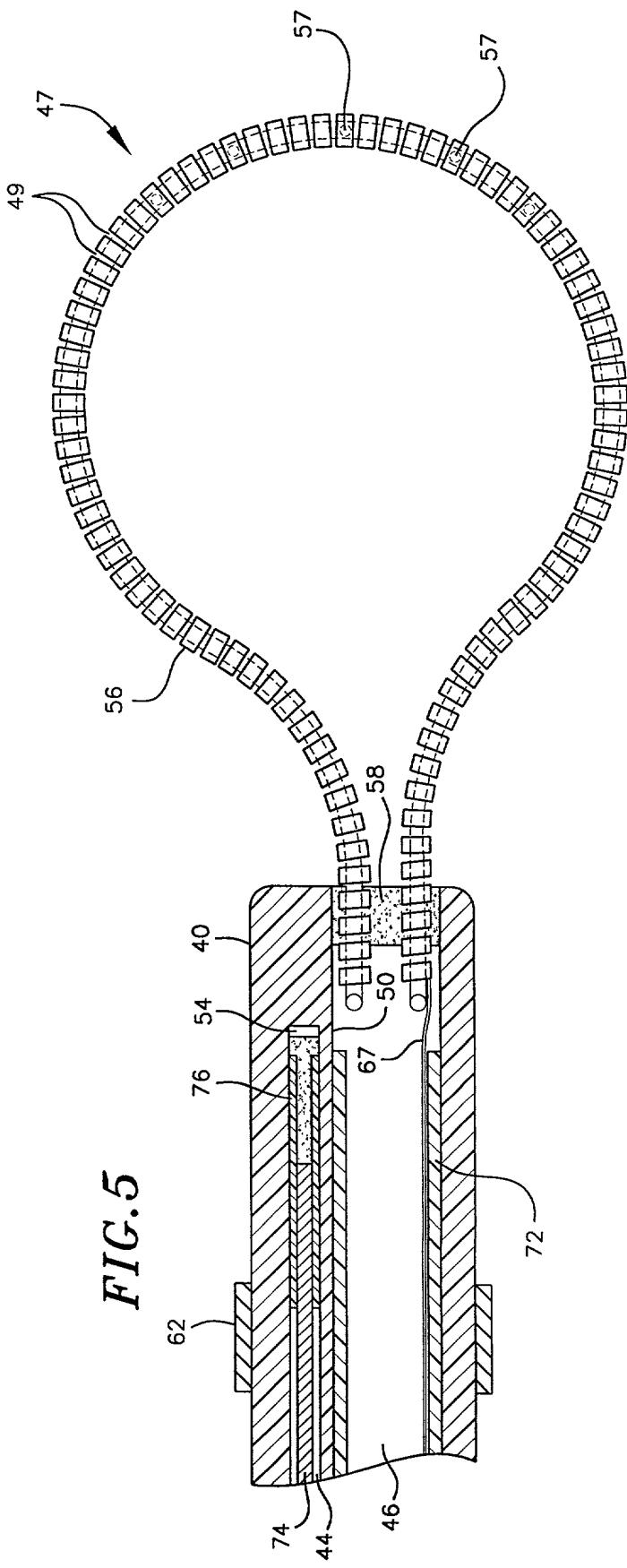


FIG. 6

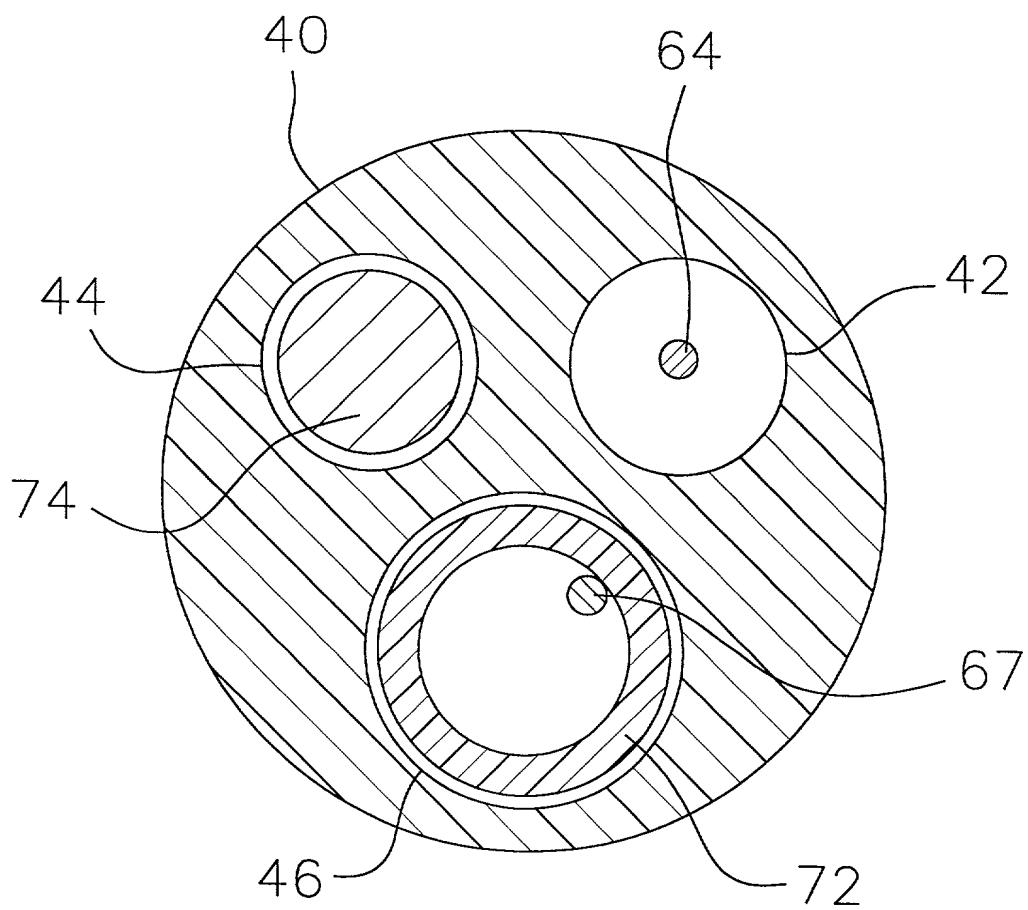


FIG. 7

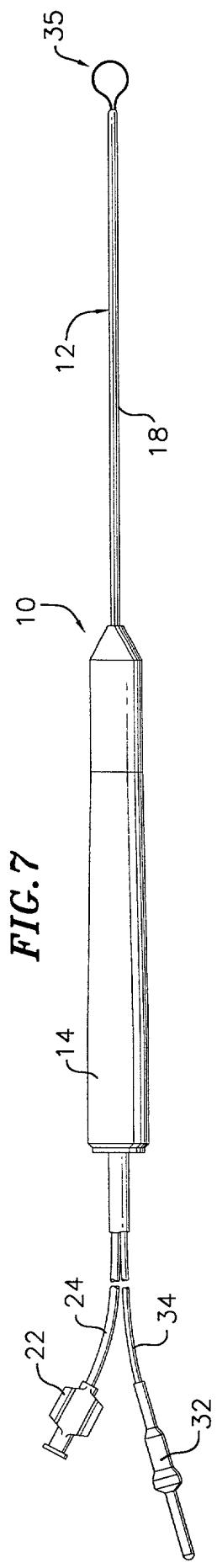
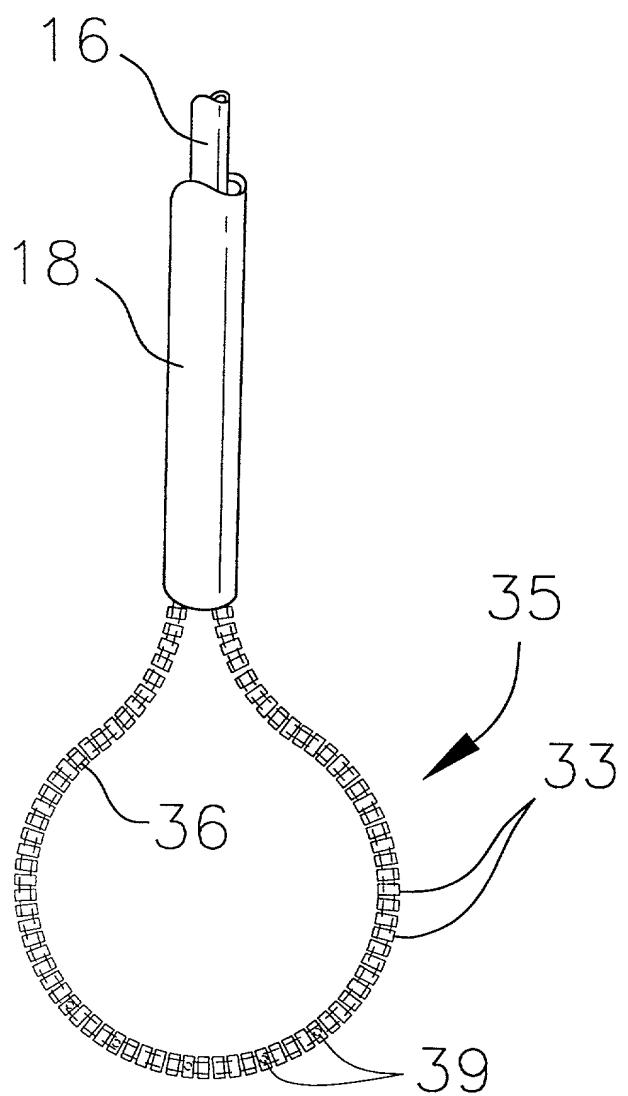


FIG. 8



**DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATIONS**

PATENT

Docket No. : 39716/KMO/W112

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled IRRIGATION PROBE FOR ABLATION DURING OPEN HEART SURGERY, the specification of which is attached hereto unless the following is checked:

was filed on as United States Application Number or PCT International Application Number and was amended on (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of the foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

<u>Application Number</u>	<u>Country</u>	<u>Filing Date (day/month/year)</u>	<u>Priority Claimed</u>
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I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below.

<u>Application Number</u>	<u>Filing Date</u>
---------------------------	--------------------

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

<u>Application Number</u>	<u>Filing Date</u>	<u>Patented/Pending/Abandoned</u>
09/370,601	August 10, 1999	Pending

POWER OF ATTORNEY: I hereby appoint the following attorneys and agents of the law firm CHRISTIE, PARKER & HALE, LLP to prosecute this application and any international application under the Patent Cooperation Treaty based on it and to transact all business in the U.S. Patent and Trademark Office connected with either of them in accordance with instructions from the assignee of the entire interest in this application;

**DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATIONS**

Docket No. 39716/KMO/W112

or from the first or sole inventor named below in the event the application is not assigned; or from _____ in the event the power granted herein is for an application filed on behalf of a foreign attorney or agent.

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The authority under this Power of Attorney of each person named above shall automatically terminate and be revoked upon such person ceasing to be a member or associate of or of counsel to that law firm.

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I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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